



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. No. 40-6563; NRC-2016-0032]

Mallinckrodt, LLC.

AGENCY: Nuclear Regulatory Commission.

ACTION: License termination; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing public notice of the termination of Source Materials License No. STB-401. The NRC has terminated the license of the decommissioned Mallinckrodt facility in St. Louis, Missouri and has approved the site for unrestricted release.

DATES: Notice of termination of Source Materials License No. STB-401 issued on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2016-0032** when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2016-0032**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):**

You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Karen Pinkston, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-3650, e-mail: Karen.Pinkston@nrc.gov.

SUPPLEMENTARY INFORMATION:

The NRC has terminated License No. STB-401, held by Mallinckrodt LLC (Mallinckrodt), for a site in St. Louis, Missouri and has approved the site for unrestricted release.

In 1961, Mallinckrodt received License No. STB-401 to extract columbium and tantalum from natural ores and tin slags. In July 1993, the NRC amended Mallinckrodt's license to a possession only license for the purpose of decommissioning and license termination. The contamination at the site was due to licensed activities consisted of natural uranium, natural thorium, and their associated progeny. The Mallinckrodt site is a 43 acre site subdivided into

ten areas called Plants. The former Columbium-Tantalum (C-T) process areas included 21 support buildings on approximately 4.2 acres, primarily located within Plant 5, but also in portions of Plants 1, 3, 6, 7, and 8.

In addition to the C-T activities conducted under License No. STB-401, the Mallinckrodt site was previously used for Manhattan Engineer District/Atomic Energy Commission (MED/AEC) activities. The U.S. Army Corps of Engineers (USACE) is responsible for remediating these portions of the site under the Formerly Utilized Sites Remedial Action Program (FUSRAP).

Mallinckrodt decommissioned the C-T project areas of the site in two phases. In Phase I, Mallinckrodt decommissioned the buildings and equipment to the extent necessary to meet the NRC's guidelines for unrestricted release in § 20.1402 of title 10 of the *Code of Federal Regulations* (10 CFR). Phase I of the decommissioning project was completed in February 2007 (ADAMS Accession No. ML070530675).

Following Phase I decommissioning, the C-T areas remaining for remediation were limited to the soil, pavement, and sewers in Plant 5, as well as portions of Plant 6 and 7. Mallinckrodt's Phase II Decommissioning Plan (DP) (ADAMS Accession Nos. ML083150652 and ML101620140) described Mallinckrodt's plan for decommissioning the remainder of the C-T project areas to meet the criteria for unrestricted release, though the remediation of portions of Plants 6 and 7 was not included in the DP and was addressed separately, as is described below. The NRC approved Mallinckrodt's Phase II DP on July 1, 2010 (ADAMS Accession No. ML091960063).

Plants 6 and 7 contained residual contamination from both licensed activities and MED/AEC activities. The MED/AEC activities in Plants 6 and 7 resulted in contamination in buildings and soil in these plants. Additionally, in Plant 6, approximately 300 cubic yards of

unreacted ore (URO) generated as part of the C-T process was buried in 10 trenches in 1972 and 1973. Plant 7 contained sewers, a grit chamber, and two wastewater neutralization basins that were used to support C-T operations.

Mallinckrodt and the USACE entered into two agreements to delineate remediation responsibilities in Plants 6 and 7. Mallinckrodt's responsibilities included the removal of the buried URO in Plant 6 and the removal of the grit chamber in Plant 7. On February 9, 2015, USACE provided Mallinckrodt with a letter acknowledging that Mallinckrodt had completed the removal of the URO and grit chambers and stating that the USACE was proceeding with remediation of these areas under FUSRAP (ADAMS Accession No. ML15090A705).

Mallinckrodt's Phase II DP requested that the NRC terminate its license in accordance with 10 CFR 20.1402 without accounting for MED/AEC contamination in demonstrating compliance with the dose limits in § 20.1402. In its approval of the Phase II DP, the NRC exempted the MED/AEC material from consideration in demonstrating compliance with license termination requirements (ADAMS Accession No. ML091960087). The basis for granting the exemption was: (1) Mallinckrodt will meet 25 mrem/year unrestricted release criteria for C-T process areas; and (2) unlicensed MED/AEC material is being remediated to the NRC's unrestricted release standards of 25 mrem/year by USACE. The dose from the residual radioactivity at the site is primarily from the direct radiation pathway, therefore the NRC concluded that an individual would not simultaneously receive a dose from both areas. The staff, therefore, concluded that it is reasonable to terminate License STB-401 after Mallinckrodt completes decommissioning activities in the C-T process areas and demonstrates that the C-T process areas at the site meet the NRC's unrestricted release criteria.

This finding is based in part on USACE's commitment to remediate the site under FUSRAP. At the time, Mallinckrodt and USACE had reached an agreement regarding

delineation of responsibility for remediating Plant 6, but had not yet agreed on the delineation of responsibility for Plant 7. Therefore, the exemption was conditioned on Mallinckrodt and USACE reaching a delineation agreement for Plant 7 before decommissioning was complete. Mallinckrodt and USACE entered into a delineation agreement for Plant 7 on October 31, 2014 (cover letter available at ADAMS Accession No. ML15041A076).

Mallinckrodt performed remediation of the C-T project areas based on their Phase II DP, conducted a Final Status Survey (FSS) and provided the NRC with a Final Status Survey Report (FSSR) documenting the residual radioactivity remaining on site for which Mallinckrodt was responsible (ADAMS Accession No. ML14177A180). Mallinckrodt subsequently provided additional information in response to the NRC's requests for additional information (ADAMS Accession Nos. ML14339A278, ML15177A051, and ML15334A417). On February 12, 2015, Mallinckrodt submitted a license amendment application requesting the use of the dose assessment approach, as well as the derived concentration guideline level (DCGL) approach (ADAMS Accession No. ML15063A404). The NRC approved this license amendment request on February 4, 2016 (ADAMS Accession No. ML15286A174).

The NRC has now completed its review of the FSSR and associated documents according to NUREG-1757, "Consolidated Decommissioning Guidance," and guidance in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (NUREG 1575). The NRC staff has concluded that the FSS design and data collected were adequate to characterize the residual radioactivity in the portions of the Mallinckrodt site where NRC regulated activities took place. The NRC staff also concluded that the data analysis and dose assessments performed are appropriate and that the projected dose from residual radioactivity in these areas is less than the 25 mrem/year dose criterion in 10 CFR 20.1402. For these reasons, the NRC staff has determined that Mallinckrodt has demonstrated that the site will meet the radiological

criteria for license termination described in 10 CFR part 20 subpart E and the exemption granted by the NRC in its approval of the Phase II DP. Therefore, Source Materials License No. STB-401 has been terminated.

Dated at Rockville, Maryland, this 9th day of February 2016.

For the Nuclear Regulatory Commission.

Michael A. Norato, Ph.D., Chief,
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs,
Office of Nuclear Material Safety and Safeguards.

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